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Report Highlights:

The new Genetically Modified Organisms (Control of Release) Ordinance became fully effective on September 1, 2011 after expiration of a 6-month grace period provided with respect to the maintenance of released living modified organisms (LMOs) in the environment. Out of practical consideration of Hong Kong's situation, the government soon after made a Notice under the Ordinance providing some exemptions. The Exemption Notice which became effective June 23, 2012 virtually allows all genetically modified papaya and LMOs that are contained in veterinary vaccines (i.e. live recombinant veterinary vaccine) to be released into the environment.

Section I. Executive Summary:

Hong Kong is one of the U.S.'s fastest growing major agricultural export markets. Currently ranking as the 7th largest market, total U.S. agricultural exports in 2011 reached a record \$3.56 billion. Within that total, Hong Kong ranked as the 4th largest market for U.S. high-value consumer-ready food and beverage exports totaling \$3.04 billion in 2011. In the first 4 months of 2012, U.S. high-value consumer-ready agricultural exports to Hong Kong reached \$955 million, representing a growth of 17 percent over the same period in 2011.

Hong Kong started to fully implement its Genetically Modified Organisms (Control of Release) Ordinance in September 2011, six months after its commencement in March 2011. U.S. food exports to Hong Kong are unlikely to be impacted by the new Ordinance and its Regulation because there are minimal, if any, U.S. exports of living modified organisms (LMOs) to Hong Kong for release into the environment. The new Ordinance requires documentation containing prescribed information for products containing LMOs. Also, prior approvals are required for products containing LMOs which are intended to be released into the environment. The Hong Kong government (HKG) introduced the new law in order to implement measures set forth under the Cartagena Protocol on Biosafey.

However, out of practical consideration and due to the prevalence of genetically modified (GM) papayas in local farmlands, the HKG soon after made the Genetically Modified Organisms (Control of Release) (Exemption) Notice under the Genetically Modified Organisms (Control of Release) Ordinance. The Exemption Notice, which came into force on June 23, 2012, exempts all varieties of genetically modified papaya and any LMO that is contained in a veterinary vaccine (i.e. live recombinant veterinary vaccine) from a provision of the Ordinance which prohibits any person from releasing a LMO into the environment or maintaining the life of a LMO in the environment without obtaining prior approval from the HKG.

The Notice also exempts two commercialized varieties of GM papaya (the variety with identifier code CUH-CP551-8 and the one with transformation event code Huanong 1) and any LMO that is contained in a veterinary vaccine from a provision of the Ordinance, which prohibits any person from importing a LMO that is intended for release into the environment without obtaining prior approval from the HKG.

The gist of the Exemption Notice is that while it is not an offence if a person grows or maintains a GM papaya in the field, he is required to obtain prior approval from the Director Agriculture, Fisheries and Conservation in order to bring in GM papaya other than the two exempted varieties. On the other hand, exemption of obtaining prior approval is provided to cases of administering or importing a live recombinant veterinary vaccine to an animal.

The new Genetically Modified Organisms Ordinance and the Genetically Modified Organisms Regulation do not have any labeling requirements for biotech food products. Hong Kong does not impose any mandatory labeling on biotech food products but continues to maintain a voluntary labeling policy. Its food safety authority – the Food and Environmental Hygiene Department (FEHD) – advised the Legislative Council in July 2008 that there was no pressing need for mandatory labeling on biotech foods because of the lack of international consensus. It pledges to further promote the Guidelines on voluntary labeling of genetically modified (GM) food, which was first launched in July 2006. As a

result, the HKG does not have any specific biotechnology regulations with regard to the labeling of biotech food products. The HKG makes no distinction between conventional and biotech foods. Thus, all are subject to the same food safety and labeling regulations.

Hong Kong has not given any indication that it plans to introduce mandatory labeling on biotech foods in the immediate future. The government's current focus is on the implementation of its first nutrition labeling law and the Pesticide Residues in Food Regulation. The HKG is also in the process of amending its regulation over veterinary drug residue in foods.

The HKG is constantly lobbied by consumer advocacy groups such as green peace and a number of Legislative Council (Legco) members to impose a mandatory labeling law for biotech food products. The Legco passed a motion urging the Government to expeditiously establish a genetically modified food labeling system for prepackaged food products by adopting a "voluntary first, and then mandatory" approach in order to safeguard consumers' right to know and to choose in 2003. The motion, nonetheless, was not binding.

Table 1. Hong Kong: U.S. Agricultural Exports to Hong Kong in 2011

Products	US\$ million	% of U.S. total exports	Ranking
All Agricultural, Fish & Forestry	3,557	2.29	7
HS1005 Corn (Maize)	8.2	0.06	42
Soybeans	31.7	0.18	27
Sub-total	39.9		
All Consumer-Oriented food products	3,043	5.22	4

Source: Global Trade Atlas – U.S. Department of Commerce, Bureau of Census

Section II. Plant Biotechnology Trade and Production:

Hong Kong does not commercially produce any biotechnology crops, nor does it conduct field trials. (However, a survey indicated that 44 percent of the locally grown papayas were of GM origin). Farming is insignificant in Hong Kong. Total land use for vegetables, flowers, field crops, and orchards are 297 hectares, 152 hectares, 20 hectares and 270 hectares respectively in Hong Kong. In 2011 agricultural production amounted to \$95.5 million, comprising \$31 million in crop production, \$36.5 million in livestock production and \$28 million in poultry production. Hong Kong's livestock and poultry industries continue to diminish, limiting future prospects for farming in Hong Kong.

In the past decade, the HKG has promoted organic farming as a niche market for Hong Kong's farmers so that they could compete to grow vegetables amidst the severe competition from lower priced conventional and organic imports from Mainland China. In an effort to promote this niche industry and support the development of organic farming, an organic certification program, through the Hong Kong Organic Resource Center (HKORC), was established in 2002. Since 2004, the HKORC has provided independent organic certification services to farmers and food processors. By the standard of HKORC, all certified organic products are GM free.

Hong Kong carries out research on biotech rice at the Chinese University of Hong Kong, although field trials are conducted in China. Professor Samuel Sun, in co-operation with the National China Hybrid Rice Research & Development Center, conducts research to improve the quality and nutritional value of super hybrid rice by utilizing transgenic plant production methods. According to Professor Sun, 50 percent of rice produced in China is of hybrid type, which has a yield that is 30 percent higher than conventional rice. Professor Sun's research project is to improve the lysine content of the super hybrid rice.

On the trade front, the few soybean users in Hong Kong require non-GM soybeans because of market-driven factors; for example, their processed products are exported to overseas markets demanding GM free ingredients. Buyers generally have a perception that all U.S. soybeans are of biotech origin. Some users of soybeans for processing report that Canadian Special Quality White Hilum (SQWH) grade soybean is popular among Hong Kong buyers. However importers claim that while SQWH soybeans are non-GM there is no identity preservation. In 2011, Canada accounted for 85 percent (\$20 million) of Hong Kong's soybean market while the U.S. merely for a share of 1.67 percent (\$393,411).

Hong Kong is not a food aid recipient and is unlikely to be a food aid recipient in the future.

Survey

The Agricultural, Fisheries and Conservation Department (AFCD) conducted a survey between 2010-2011 drawing 800 crop samples from markets and farms to assess the presence of GM ingredients in crop supplies, of which 27 samples were found with GM ingredients. Papaya was the crop identified with the highest percentage of GM origin. Nine out of 24 imported papaya samples or 38 percent were GM products. Three papaya samples were of U.S. origin, two of which were GM products originating from Hawaii. The GM percentage of locally grown papayas was even higher at 44 percent.

The sample pool consisted of 77 U.S. products, of which 7 were biotech products. Apart from the two papaya samples mentioned above, the other five GM products were animal feed samples which were identified from a pool of 11 animal feeds samples.

As AFCD is responsible for agriculture and fisheries in Hong Kong, the survey does not cover any processed foods such as breakfast cereals and chips.

For more information on the survey, please see <u>GAIN report - Survey Results Prompt HKG to Seek Exemptions to GM Ordinance</u>.

Section III. Plant Biotechnology Policy:

The Food and Health Bureau (FHB) is responsible for the policy direction in regards to biotech foods. The Food and Environmental Hygiene Department (FEHD) is the Bureau's department for food safety, which administers its programs through its Center for Food Safety. Administration of policies relating to agricultural production falls under the portfolio of the Agricultural, Fisheries and Conservation Department (AFCD) within FHB.

Hong Kong started to implement its Genetically Modified Organisms (Control of Release) Ordinance and the Genetically Modified Organisms (Documentation for Import and Export) Regulation in March 2011 with a six- month grace period which ended on August 31, 2011. The HKG introduced the new law in order to implement measures set forth under the Cartagena Protocol on Biosafey. China has been a party to the Convention and the Protocol since 1993 and 2005 respectively. They are now extended to Hong Kong with the implementation of the new law.

The Ordinance stipulates that the importation of LMO to Hong Kong (except for exemptions provided by the Exemption Notice) with the intention to be released into the environment requires to obtain prior approval from the Agriculture, Fisheries and Conservation Department. (Note: GMO in the Ordinance refers to living modified organisms.) The AFCD maintains a LMO online register which keeps non-confidential information received pertaining to the LMO approval applications. As of July 2012, the HKG has not received any such application yet.

Under the new law, there are prescribed documentation requirements for all shipments containing LMOs. The HKG emphasized that the documentation requirements adhere strictly to the requirements stipulated by the Cartagena Protocol.

According to the subsidiary regulation, documentation is required for the following categories of LMOs:

- a) LMOs intended for direct consumption as food, feed or for processing; (LMOs-FFP)
- b) LMOs intended for contained use; and
- c) LMOs intended for release into the environment.

The following paragraphs summarize the information required for LMO shipments for various purposes.

a) For LMOs-FFP

- If the identity of the LMO is known, the shipment contains such a LMO; if the identity of the LMO is not known, the shipment may contain such a LMO;
- The LMO is not intended for release into the environment;
- The common name, scientific name and, where available, commercial name of the LMO;
- The transformation event code of the LMO or, where available, its unique identifier code; and,
- The details of the importer or exporter (such as name, address and contact information) for further information.

b) For LMOs intended for contained use

- The shipment contains a LMO which is intended for contained use;
- The common name, scientific name and, where available, commercial name of the LMO;
- The name, address and contact details of the consignee and the exporter or importer;
- The requirement, if any, for the safe handling, storage, transport and use of the LMO. If there is no requirement as stated above, a statement that there is no such requirement; and
- New or modified traits or characteristics of the LMO such as event of transformation, risk class, specification of use, and any unique identification, where available, as a key to accessing information in the Biosafety Clearing-House.
- c) For LMOs intended for release into environment
 - The shipment contains a LMO;
 - The common name, scientific name and, where available, commercial name of the LMO;
 - The traits and characteristics of the LMO, including transgenic traits and characteristics such as event of transformation or, where available, a reference to a system of unique identification;
 - The requirement for the safe handling, storage, transport and use of the LMO under applicable existing international instruments, local legislation or any agreement entered into by the exporter or importer;
 - If there is no requirement as stated above, a statement that there is no such requirement;
 - The name, address and contact details of the exporter or importer;
 - The details of contact point for further information, including an individual or organization in possession of information, in case of emergency;
 - The risk class and import approval for the first transboundary movements of the LMO; and,
 - A declaration that the movement of the LMO is in conformity with the requirements of the Protocol and which is applicable to the exporter.

There is no specific requirement regarding the form of documentation accompanying LMO shipments. The use of a commercial invoice or other documents required or utilized by existing documentation systems, or documentation as required by other local legislation and / or administrative frameworks is acceptable as documentation that should accompany the LMO shipments. Such documentation should include the information specified in the paragraphs above (as the case may be) and allow for easy recognition, transmission and effective integration of the information requirements. In addition to commercial invoices, other forms of documentation that are acceptable include import/export manifests;

and licenses or certificates issued or required under other legislation (e.g. phytosanitary certificates).

The AFCD provides guidelines on documentation requirements and documentation samples.

Exemptions to GM Ordinance

The Genetically Modified Organisms (Control of Release) Ordinance which became effective March 2011 requires that both the local production and importation of GM crops with the intention to be released into the environment obtain approval from AFCD. Upon the expiry of the grace period, any person growing GM crops which have not been approved by the AFCD will be in violation of the law, except for exemptions provided by the Exemption Notice.

The Genetically Modified Organisms (control of Release) (Exemption) Notice made under the Genetically Modified Organisms (Control of Release) Ordinance took effect June 23, 2012.

The Notice exempts all varieties of genetically modified papaya and any LMO that is contained in a veterinary vaccine(live recombinant veterinary vaccines) from the application of an Ordinance's provision that a person must not knowingly cause a LMO to be released or maintain the life of a LMO in the environment.

The Notice also exempts two commercialized varieties of GM papaya (GM papaya with the unique identifier code of CUH-CP551-8 and GM papaya with the transformation event code of Huanong 1), and live recombinant veterinary vaccines from the application of an Ordinance 's provision that a person must not knowingly import a LMO that is intended for release into the environment.

The rationale for the exemption was that given the low risk of the exempted LMO to the local biodiversity, the exemption would avoid creating undue nuisance and disturbance to the public and cater for the need of the application of live recombinant veterinary vaccines in emergency situations such as an outbreak of a pandemic disease.

Based on a risk assessment conducted by the HKG, the GM papaya is unlikely to pose any adverse biosafety effect on the biological diversity of the local environment because papaya is an exotic species and that it does not have any close relatives in Hong Kong. As such, the release of GM papaya to the environment is unlikely to pose any risk to local biodiversity. Due to the species barrier, the inserted genes of GM papaya cannot pass on to local wild plants.

The HKG decided to exempt local papaya growers from applying for approval for releasing GM crops into the environment resulted from the wake of a survey indicating over 44 percent of locally grown papaya are GM products. Hong Kong has little farming. Most locally produced papayas are backyard crops for self consumption with no or little commercial value. It is envisaged that many of these farmers are senior citizens living in the suburbs and may not be aware of the new ordinance. Even if they have heard of it, they might not bother to apply for approval with an application fee of over US\$1800 nor would they have the expertise to submit the necessary information such as a risk assessment of the crops.

The HKG realized that enforcement of the new law with respect to the growing of papayas would be a challenge. Therefore, they decided to provide an Exemption Notice under the new ordinance by which it will no longer be an offence for the growing of GM papayas even without obtaining the approval from the HKG.

Labeling of Biotech Products - Voluntary Labeling Approach

There is no legislation for mandatory labeling for biotech foods or feeds. The FEHD released guidelines for voluntary labeling of biotech foods in 2006 in order to answer the public's call for consumers' right to make informed choices. In 2008, the HKG announced that there is no need for a mandatory labeling law in Hong Kong based on an evaluation exercise of the voluntary labeling scheme. The HKG said they are not adopting a mandatory scheme because currently there is no international consensus on mandatory labeling. Their declared position is to closely monitor international development on this issue and to promote the voluntary guidelines to the trade for more widespread adoption.

The guidelines were formulated by a working group established under the Center for Food Safety, with members coming from various sectors including manufacturing, wholesale, retail, consumer groups and government departments. The guidelines are advisory in nature and do not have any legal effect. Adoption is entirely voluntary and is not binding. The guidelines apply to prepackaged food.

The guidelines are based on the following four principals:

- The labeling of biotech food will comply with existing food legislation.
- The threshold level applied in the guidelines for labeling purpose is 5 percent, in respect to individual food ingredients.
- Additional declaration on the food label is recommended when significant modifications of the food, e.g. composition, nutrition value, level of anti-nutritional factors, natural toxicant, presence of allergen, intended use, introduction of an animal gene, etc, have taken place.
- Negative labeling is not recommended.

As the guidelines are voluntary, U.S. food exports should not be affected if they choose not to have any biotech labeling. However, it should be noted that the HKG does not encourage negative labeling when no biotech counterparts of the respective products exist. Also, the HKG does not encourage negative labeling using very definite terms such as:

- GMO free,
- Free from GM ingredients, etc

For products with such definite negative labeling, the government may take the initiative to test the products against GM ingredients and a zero tolerance will be adopted for testing purposes. If products are found to have misleading labeling, a retailer may be subject to prosecution under Section 61 – False Labeling and Advertisement of Food or Drugs of Chapter 132 Public Health and Municipal Services Ordinance.

If the trade chooses to apply negative labeling, the government advises to use less definite terms such as "sourced from non-GM sources" (which contains less than 5 percent of GM content) and to have documentation to substantiate such declaration. For more details, please refer to <u>GAIN Report HK#6026</u>.

After a year of implementing the voluntary system, the HKG conducted a survey to assess the effectiveness of the voluntary scheme in 2007. The evaluation result showed that all the samples indicating biotech status carried negative labels and the majority of the negative labels are backed up by documentary proof. Also, for the samples subject to laboratory testing, all tested samples bearing negative labels did not contain any detectable biotech material or specific biotech events.

Section IV. Plant Biotechnology Marketing Issues:

Hong Kong's 'green' groups, some consumer organizations and a few Legislative Council (Legco) members have been advocating for mandatory labeling of biotech foods for many years. Their rationale is based on consumers' "right to know". Food safety or science is not their key argument. They also expressed doubts whether the existing voluntary labeling is effectively implemented by the trade. Lobbying by green groups and consumer organizations has gained support of certain Legco members. In January 2000, Legco adopted a motion to "draw on the experience of most member states of the European Union and expeditiously legislate for a labeling system" and to "conduct strict examinations and tests" on biotech foods. In June 2003, Legco passed a motion calling on the government to expeditiously establish a "voluntary first, and then mandatory" approach to a labeling system for biotech foods. However, the results of motion are not binding for the HKG.

The food industry has generally opposed to mandatory labeling of biotech foods on the grounds that it would limit the choices of consumers, reduce variety of food supplies to Hong Kong and add burden to consumers and the industry alike. Hong Kong's retailers have said they would not import any products that carried a GM label. They believe that consumers will not choose GM products when there are other choices available.

On the whole, Hong Kong consumers are not concerned about foods containing biotech ingredients. There have not been any strong actions in the public urging the HKG to adopt mandatory labeling for biotech foods in recent years. Prices and nutritional values are of bigger concern in general. However, local food processors would specify the use of non-biotech soybeans particularly if their products are exported overseas.

Section V. Plant Biotechnology Capacity Building and Outreach:

ATO believes that educating HKG officials, legislators, educators and media on the science-based principles and consumer benefits of biotechnology is the most effective way to maintain reasonable, science-based rules and regulations. Realizing that there is a lack of understanding in regards to biotechnology in Hong Kong, ATO launched a biotech outreach program in 2008 educating relevant stakeholders with a science-based approach on biotechnology.

ATO invited Dr. Wayne Parrott, Professor of Plant Genetics at the University of Georgia, to give a

series of five biotech lectures to different audiences which reached nearly 1,200 people. To achieve our objective of providing a science-based introduction of GM foods to relevant stakeholders, the outreach events included government officials who are in charge of food safety and labeling, key retailers, traders, importers and food manufactures. Also included on our participant lists were teachers and students from secondary schools in Hong Kong and Macao. Educators were provided with a copy of the presentation to use as a resource for teaching.

Section VI. Animal Biotechnology:

Animal farming is insignificant in Hong Kong. There is no genetic engineering and cloning being done on Hong Kong's limited animal farms. Importation of transgenic animals is limited to two types of aquarium fish: zebra fish and rice fish. They are imported at a very insignificant amount as pet fish.

With the implementation of Genetically Modified Organisms (Control of Release) Ordinance, the importation of live transgenic animals, which are to be released into the environment, are required to obtain prior approval from the AFCD. If they are imported for contained use, prior approval is not required though declaration has to be made on import documents.

However, the new regulation does not have any impact on products that contain non-living GM ingredients.

The HKG did not comment on FDA's Risk Assessment on products from cloned animals and their progeny in January 2008. However, in December 2006 when FDA issued three documents on the safety of animal cloning (a draft risk assessment; a proposed risk management plan and a draft guidance for industry), the HKG immediately wrote to ATO enquiring about the U.S. control measures on production/exportation of meat and milk products from cloned animal, and whether any such product has been exported to Hong Kong. It specifically cited FDA's request in the proposed risk management plan for industry's voluntary moratorium on introducing products of cloned animals into commerce. While the HKG does not have any immediate plan to change their import policies on food products for cloned animals, we expect that certain legislative Council members, media and consumers group will press the HKG to look into the issue if products of cloned animals are exported to Hong Kong. The HKG may be sensitive to political pressure on this issue. Post believes any new requirement would likely seek to label the food products as cloned as opposed to banning them.

With regard to cloning animal technology, the HKG has no plans underway to conduct a risk assessment.